Boehringer Ingelheim

2138 '03 APR 23 A9:13

Boehringer Ingelheim Corporation

Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane
Rockville, MD 20852

March 19, 2003

**Comments Regarding the FDA Draft Guidance Document "Part 11, Electronic Records; Electronic Signatures - Scope and Application**

Paul C. Lang
Telephone 203-798-5347
Telefax 203-778-7327
E-Mail plang@rdg.boehringer-ingelheim.com

900 Ridgebury Rd/P.O. Box 368
Ridgefield, CT 06877-0368
Telephone (203) 798-9988

To Whom It May Concern Within the FDA:

Boehringer Ingelheim, a progressive worldwide pharmaceutical organization would like to commend the Agency on their recognition of the need to step back and reanalyze the original intent of 21 CFR Part 11 and problematic issues the current understanding of the ruling has imposed on the Pharmaceutical Industry.

While we at Boehringer Ingelheim feel the new guidance will indeed go a long way to allow the Industry to more easily comply with the regulation and the current thinking of the Agency, our internal review of the draft guidance has drawn questions and concerns we would request the Agency to further clarify.

In order to make the review of Boehringer Ingelheim comments on the draft guidance as easy as possible, we have submitted the comments in a table format that identifies the line number(s) the comments were drawn from and the comment.

We at Boehringer Ingelheim look forward to the publication of a response from the Agency regarding these and other valuable input from the Industry and the final guidance document.

With Kind Personal Regards,

Paul C. Lang

Paul C. Lang
Director, Part 11 Management
North America

030-0060 C 7

Boehringer Ingelheim

| Line Number | Question - Concern |
|---|---|
| 31 - 39 | We understand that the purpose of this guidance is to establish the FDA's current way of thinking regarding a narrow interpretation of Part 11 and enforcement discretion while the Agency re-evaluates 21 CFR Part 11. Can the Agency give Industry some perspective regarding how long this will take? |
| 31 - 39 | The guidance indicates the FDA will consider a narrow enforcement of Part 11 during the re-evaluation period. If industry moves forward on the context of this guidance rather than waiting for a revised Part 11 ruling, what is the impact on Industry if the FDA reverts back to their original enforcement? |
| 36- 38 | The draft guidance indicates many times that the agency will not normally take regulatory action. Can the guidance be more precise as to under which conditions the FDA will take regulatory action? What can be considered as normally and unusual? |
| 41 - 44 | We believe the definition given in the guidance could lead one to believe that the only criteria for classifying a computer system as a legacy system is if it were put into production use prior to August 20, 1997. What about systems that were in operation prior to August 1997 but has had upgrades and were re-validated since that time? |
| 46 - 50 | Other than indicating there will be a narrow interpretation of Part 11 and the use of discretion in enforcement, what guidance can the FDA offer to industry regarding Part 11? Previous tools are no longer available (recalled guidance documents). Are 483s and Warning Letters that cited Part 11 non-compliance previous to February 20 still appropriate references? |
| 62 - 68 | With all of the current guidance documents recalled and the compliance policy no longer in force it seems FDA field investigators have little to use for ground of enforcement. Does the FDA plan to revise the Compliance Policy Guide and if so when? |
| 70 – 79 | The recalled FDA Part 11 guidance documents were long awaited. Will any of these guidance documents be re-issued or other new guidance documents be issued? |
| 70 - 79 | The FDA guidance documents identified in the draft guidance are still found on the FDA WEB site. When will the documents be pulled from the WEB site? |
| 104 - 108 | During the re-examination period the possibility exists for Industry to create new compliance issues by establishing a more liberal position on what would constitute Part 11 compliance. Does the FDA know if the provisions that will (or may) be revised are the same or broader than the attributes this guidance indicates will follow enforcement discretion? |
| 149 - 156 | We are not clear on what would constitute using a paper record in lieu of an electronic record. In the case of using a paper print out in lieu of electronic records; is it the expectation that the electronic data be deleted or is simply using it for regulated activities while maintaining the electronic record acceptable? |

Boehringer Ingelheim

| Line Number | Question - Concern |
|---|---|
| 149 - 156 | Can the Agency give some examples of what does and what does not constitute "incidental use" of a computer system? Is it nothing more than the "typewriter" example Mr. Motise often cited? |
| 149 - 156 | In many laboratory environments people use paper records (created by printing) but keep electronic records in addition to paper. In many cases, it is just for archiving purpose and/or for making searches easier. But no decision is made (it is not a normal activity of the people) and no change is made. In that case, does Part 11 apply? Can we consider this use as a merely incidental use of the electronic record and not as performing a regulatory activity, or would the data have to be deleted from the system in order to avoid having to comply with Part 11? |
| 163 - 190 | In this section the Agency identifies 3 types of electronic record classes and within each class, instances where the electronic record would or would not be a "Part 11" record. Considering the lack of any other guidance now available it would be extremely valuable if the FDA could indicate examples of these classes specifically. |
| 163 – 190 | Does the Agency intend to enforce a broader scope of 21 CFR 820 (medical devices) on the traditional GxP environment? |
| 196 - 201 | Considering that computer systems validation has been an Industry requirement long before Part 11 became a rule and that it generally does not require costly technical remediation, we do not understand why the FDA feels that a relaxed position of enforcement is appropriate? Please explain why the Agency feels Industry can not readily meet the requirements expected for computer systems validation. |
| 203 - 210 | In this paragraph the Agency indicates that even if a predicate rule does not dictate that a computer system must be validated, it nonetheless may be important to validate that system. Is the Agency indicating that Pharmaceutical companies can be cited for not validating computer systems that otherwise are not required to be validated by predicate rule. This is furthermore confusing when the relaxed enforcement position of the FDA has indicated regarding computer validation. Could the Agency make a clearer indication of what is meant by this paragraph? |
| 212 - 214 | What is the FDA position regarding GAMP4 instruction on Part11 compliance in light of the fact that GAMP4 was published prior to this guidance? Is this an official recognition of the GAMP4 and giving it a status of being equivalent to FDA guidance? |
| 275 - 279 | The Agency indicates they normally would accept the archiving of data to non-electronic media. Once source data is archived using one of the identified methods – can the source data be deleted? |